

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John Holman on March 25, 2008.

The application has been amended as follows:

In the claims:

Claims 10-16 have been canceled without prejudice.

Claim 17, line 4, "is immunoreactive" has been replaced with --binds--.

Claim 17, line 5, the "comprised in amino acid sequence" has been replaced with --in the amino acid sequence--.

In claims 18-25, line 1 of the claims, "A method as claimed in" has been replaced with --The method of--.

2. The following is an examiner's statement of reasons for allowance: the prior art fails to teach or suggest a method for detecting collagen type II fragments using an antibody that binds to HRGYPGLDG (SEQ ID NO:1) or epitopes therein.

Holmdahl et al. (US 7,148,020 B2, of record) teaches the peptide GHRGYPGL, which includes an epitope within SEQ ID NO:1 plus an additional N-terminal glycine residue (see, e.g.,

Art Unit: 1641

Holmdahl et al. at column 12, lines 16-17). However, the reference teaches using the peptide in a method to detect antibodies that have affinity for collagen type II epitopes (see, e.g., column 19, lines 32-37), and therefore fails to teach raising antibodies against this sequence and using the resulting antibodies in a method to detect collagen type II fragments.

Furthermore, Holmdahl et al. teaches the above sequence in the context of complexes of three polypeptides arranged in a triple helical conformation (see, e.g., column 9, lines 9-12). The evidence of record indicates that the SEQ ID NO:1 epitope is a neoepitope that is buried in the triple helix collagen structure, and only accessible for antibody binding in the context of unwound collagen fragments (see the previous Office action at pages 7-14 and Applicant's arguments in the Reply of 12/26/07 at pages 2-3 and 7-11). Consequently, even if one of ordinary skill in the art were to raise antibodies against polypeptide compositions of Holmdahl et al. that included the related sequence GHRGYPGL, the resulting antibodies would not bind to epitopes within SEQ ID NO:1 since this epitope is inaccessible in triple helix collagen.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/  
Examiner, Art Unit 1641

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641